

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Dov Malonek et al. : Examiner: G.R. Evanisko
Serial No.: 09/849,637 : Group Art Unit: 3762
Filed: May 4, 2001 : Confirmation No.: 6911
For: **Multi-Electrode Lead**

DECLARATION UNDER 37 C.F.R. §1.132

I, Shawn Moaddeb, hereby declare and say, that:

Background and Experience

1. I have a Bachelor of Science degree in Physics and Applied Engineering and a Masters of Science degree in Physics. Both degrees were received from Pittsburg State University.
2. I have over twenty-five (25) years experience in the medical device industry including managing and resolving programs and launching new products.
3. I have applied for over 40 patents in the medical device area, including improvements in leads for pacemakers or defibrillators.
4. I am currently on the Board of Directors of Oncogenics, Inc., a company involved in developing cancer diagnostics and products.

5. I am currently on the Board of Directors of Ellipse Technologies, Inc., a company focused on non-invasive therapy for obesity and GERD.
6. I am currently on the Board of Directors of MiCardia, Corp., a company focused on non-invasive simultaneous imaging and therapy based on external activation. At MiCardia, I have been responsible for all activities related to the development of next generation heart remodeling technologies. I have filed twenty-two patent applications in this area.
7. I spent ten years as an engineer and program manager specializing in medical device leads research and development.
8. A summary of my experience is attached hereto as Exhibit A.
9. I am not and have never been an employee of Impulse Dynamics N.V., the assignee of U.S. Patent Application 09/849,637 (the "Application"). I have been engaged by Impulse Dynamics N.V. to provide this Declaration.

The Application and Rejection

10. I have read and am familiar with the text of the Application.
11. I understand that the U.S. Patent Examiner examining the Application has taken the position that one with ordinary skill in the art would not be able to produce an electrode with a capacitance of from greater than 300 to less than 3000 microfarads.

12. As someone with experience in the field of creating leads for modifying the activity of at least a portion of a tissue of human cardiac muscle, it is my opinion that one with ordinary skill in this art would be able to produce an electrode having a capacitance greater than 300 microfarads and less than 3000 microfarads.

Teachings From Prior Art Patents

13. U.S. Patent 4,602,637 to Elmqvist and Mund ("Elmqvist") discloses a heart pacemaker system in this art. A copy of Elmqvist is attached as Exhibit B.
14. Elmqvist describes a method for creating porous electrodes using materials with particle sizes, or a porosity, in a range of 2 microns to 100 microns to create a double layer capacitance in a range of 10 millifarads to 100 millifarads per square centimeter.
15. In Elmqvist, an electrode with a double layer capacitance of up to 0.1 F/cm^2 is achieved using such a porous coating. A glassy carbon may also be used as is discussed in German Publication 2613072 - referenced in Elmqvist. Such a capacitance is even higher than that claimed. Lesser capacitance values may be easily obtained by simply generating thinner, or less porous electrodes.
16. U.S. Patent 4,611,604 to Botvidsson and Munch ("Botvidsson") also discloses the provision of electrodes with a capacitance in the range of 10 millifarads to 100 millifarads per square centimeter and discloses using materials with porous coatings for ring and tip electrodes to increase capacitance to 0.1 F/cm^2 . In

Botvidsson, the particle sizes of the materials are between 1 micron and 100 microns. A copy of Botvidsson is attached as Exhibit C.

17. I understand that the Examiner has made reference to U.S. Patent 5,824,016 to Ekwall ("Ekwall"). Ekwall is not relevant to indicate whether one with ordinary skill in the art would be able to produce an electrode with a capacitance of from greater than 300 to less than 3000 microfarads.
18. The disclosure of Ekwall discloses techniques for minimizing current leakage.
19. The coating used in Ekwall is limited in capabilities as it relies on oxide formation.
20. Oxide formation is not very effective due to its capacitance limitation. It is therefore understandable that the capacitance values shown in Ekwall are only in the range of 1-15 microfarads.
21. Oxide formations are usually very thin without high surface area. To increase capacitance, a porous material used to increase surface area may be utilized as is shown in Elmqvist and Botvidsson.

Background Technology

22. There is a known linear relationship between capacitance and both porous coating thickness and physical morphology. Stated another way, those with ordinary skill in the art know that higher porosity and thicker material result in higher capacitance values.

23. At the time of the filing of the Application, typical pacemaker tip electrodes were in the range of 4-8mm² and a ring electrode was 5 to 20 times larger.
24. TiN electrodes developed in the late 1980s used a reactive sputtering technique and achieved a high capacitance value by creating diamond like morphology with a thickness of around 10-30 microns.
25. Capacitance was additionally increased by providing a base metal from Pt/Ir covered with Pt/Ir particles in the range of 25-50 microns, and then the particle/base combination was coated with TiN. This effectively increased the surface area without increasing physical geometric area.
26. Thus, one with ordinary skill in the art could easily coat electrodes to have a desired capacitance, such as from about 300 to about 3000 microfarads, simply by picking materials stated in the Application - such as TiN, IrOx, carbon, etc. and use various techniques for deposition such as reactive sputtering, ion-plating, sintering, vacuum deposition, ion-implantation, electrochemical plating, etc., to create diamond like or other morphologies with different thicknesses. If TiN is used, the resultant thicknesses of porous TiN would typically be around 10 to 30 microns.
27. There are known companies who provide such services, such as Wilson Greatbach and Heraeus, who will produce an optimized coating based on a customer's capacitance requirements.

28. There are also various known biocompatible materials that may be used for the coating.
29. One with ordinary skill in this art would be aware of other techniques and materials for producing the claimed lead and would be aware of numerous published articles and scientific abstracts describing the same.

Example

30. I will now provide an example of how one with ordinary skill in this art would be able to produce an electrode with a capacitance of from greater than 300 to less than 3000 microfarads. It should be clear that other methods are known and available:
31. A 90%Pt / 10%Ir metal may be used as a base.
32. If a tip electrode is being formed, a center of the base may be covered with sintered 90%Pt / 10%Ir particles ranging in size from 40-60 microns. If a ring electrode is being formed, the porous 90%Pt / 10%Ir need not be used.
33. A TiN layer is then applied in two steps: First, a dense TiN coating with a thickness of 0.5 to 2 microns may be applied. And second, a porous TiN coating with particle sizes and a thickness in the range for 10-100 microns may be applied.
34. The above steps create a diamond like structure. Microporous structures like these yield very large effective surface area with increased capacitance and decreased polarization potential.

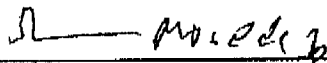
35. The TiN coating may be produced by evaporating high purity titanium using a DC or RF magnetron sputtering process. An electron beam in a presence of a reactive gas (such as pure Nitrogen or in combination with Argon) in a reduced pressure chamber will produce a fine, molecular scale vapor. The base material will be placed in the sputtering chamber with the sputtering target made from Ti.
36. Typical sputtering parameters include: sputtering base pressure 5.0×10^{-4} Pa and a total Ar + N₂ gas pressure of 3.0×10^{-1} Pa. A substrate to target distance may be around 0.05 meters. A substrate biased voltage of -200V may be used.
37. A user may continuously monitor impedance, and, once desired capacitance is reached, deposition may be terminated.
38. For the sintered porous Pt/Ir metal, metal powders can be mixed with special binders to form a slurry that can be applied to base metal substrates or used to form net shape components.
39. Subsequently, the metal base with the slurry material will be sintered in a sintering furnace at a temperature below the melting point of the metal but high enough to soften the metals to adhere to each other.
40. The above process has been used in medical devices for over 20 years.
41. A verification of the capacitance of the lead may be performed by verifying the polarization of the electrode.

Conclusion

42. As set forth above, I would be able to produce an electrode with a capacitance of from greater than 300 to less than 3000 microfarads.
43. It is also my opinion that others with ordinary skill in this art would be able to produce an electrode with a capacitance of greater than 300 to less than 3000 microfarads.

I declare under the penalty of perjury that the foregoing is true and correct.

May 29, 2006



Shawn Moaddeb